K090066

WSM Wear Safe (Malaysia) Sdn.Bhd. (Company No.204396-X)

FDA 510(k), Premarket Notification : 510(k) Summary of Safety and Effectiveness Information

1.0 Submitter:

MAY 15 2009

WEAR SAFE (MALAYSIA) SDN. BHD.
Lot PT 13726, Jalan Haji Salleh, Off Jalan Meru, 41050 Klang,
Selangor Darul Eshan,
Malaysia.

Telephone No.: +603 3392 3088
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2.0 Contact Person:

Contact: Mr. SH TAN
E-mail: shtan@kossan.com.my
Telephone No.: +603 3291 2657
Fax No.: +603 3291 0584

3.0 Name of Device:

Trade Name: Powder Free Polymer Coated Latex Surgical Gloves, Sterile, with Protein Labeling claim of 50 micrograms per dm^2 of glove or less of water soluble protein.
Common Name: Surgeon's Glove
Classification Name: Surgeon's Glove

4.0 Identification of The Legally Marketed Device:

The Powder Free Polymer Coated Latex Surgical Gloves, Sterile, with Protein Labeling claim of 50 micrograms per dm^2 of glove or less of water soluble protein, Class I surgeon's gloves, 79KGO, meets all of the requirements of ASTM D3577 Standard Specification for Rubber Surgical Gloves for Medical Application.

5.0 Description of Device:

The Powder Free Polymer Coated Latex Surgical Gloves, Sterile, with Protein Labeling claim of 50 micrograms per dm^2 of glove or less of water soluble protein will meet all the current specification for ASTM D3577.

6.0 Intended Use of the Device:

The Powder Free Polymer Coated Latex Surgical Gloves, Sterile, with Protein Labeling claim of 50 micrograms per dm^2 of glove or less of water soluble protein is a disposable device intended for medical purposes that is intended to be worn by operating room personnel to protect a surgical wound from contamination.

7.0 Summary of The Technological Characteristics of The Device:

The Powder Free Polymer Coated Latex Surgical Gloves, Sterile, with Protein Labeling claim of 50 micrograms per dm^2 of glove or less of water soluble protein possesses the following technological characteristic (as compared to ASTM or equivalent standards):

Characteristic	Standards	Device Performance
Dimensions	ASTM D3577 - 06	Meets
Physical Properties	ASTM D 412 – 06ae1	Meets
Freedom from pin-holes	ASTM D 5151 - 06	Meets
Powder Free Residue	ASTM D 6124 - 06	Meets
Biocompatibility	Dermal Sensitization (as per ISO 10993-10)	Not a contact skin sensitizer
	Primary Skin Irritation Test (as per ISO 10993-10)	Not a primary skin irritant

8.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data

The performance test data that support a determination of substantial equivalence are described above.

9.0 Substantial Equivalent Based on Assessment of Clinical Performance Data

Clinical data are not needed for market cleared surgical gloves.

10.0 Conclusion

It can be concluded that the The Powder Free Polymer Coated Latex Surgical Gloves, Sterile, with Protein Labeling claim of 50 micrograms per dm^2 of glove or less of water soluble protein is safe and effective for use and will perform according to the glove performance standards referenced in Section 7 above, thereby meeting ASTM standards, FDA requirements, and the labeling claims for the product.
Consequently, this device is substantially equivalent to current marketed devices.
This summary will include any other information reasonably deemed necessary by the FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2009

Mr. SH Tan
Wear Safe (Malaysia) Sdn.Bhd.
Lot 13726
Jalan Haji Salleh
Batu 5¼ Off Jalan Meru
41050 Klang
Selangor Darul Ehsan
MALAYSIA

Re: K090066
Trade/Device Name: Powder Free Polymer Coated Latex Surgical Gloves, Sterile, With Protein Labeling Claim of 50 Micrograms Per DM^2 Glove Or Less Of Water Soluble Protein.
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: I
Product Code: KGO
Dated: April 27, 2009
Received: April 30, 2009

Dear Mr. Tan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

WSM Wear Safe (Malaysia) Sdn.Bhd. (Company No.204396-X)

INDICATIONS FOR USE

Applicant: WEAR SAFE (MALAYSIA) SDN. BHD.

510(k) Number (if known):

Device Name: Powder Free Polymer Coated Latex Surgical Gloves, Sterile, with Protein Labeling claim of 50 micrograms per dm^2 of glove or less of water soluble protein.

Indication For Use: A powder free polymer coated latex surgical glove is a disposable device made of natural rubber material intended to be worn by operating room personnel to protect a surgical wound from contamination.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090066

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